caBIG
Tissue Banks and Pathology Tools Workspace (TBPTWS)
Requirement Specifications Survey

I. **Respondent Contact Information**
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Role (e.g. developer, adopter): adopter

II. **Document Purpose**

The purpose of this document is to collect information regarding the specifications of existing specimen bank data management systems and the perceived requirements of any new system that would be developed and adopted for the cancer Biomedical Informatics Grid (caBIG). In order to minimize the time and effort required to collect pertinent information, a series of guided responses are provided which should be answered as indicated. In the event that the options provided do not adequately characterize features of the data management system, the respondent is asked to provide brief details regarding the unique aspects of their system. **All information obtained from this survey will be kept confidential and will only be distributed in de-identified or aggregate form**. This information will be utilized by the caBIG TBPTWS development team to guide the construction of a data management system that can be easily deployed or adopted by all caBIG members. Prior to the onset of building this system, a formal "Requirements Specification" technical document will be produced and will be available for review and comment.

III. **Scope of Specimen Bank**

A. Please indicate the nature of the specimen bank served by your data management system (circle all that apply):
  1. Specimen bank support for multiple clinical trials, same organ system
  2. General archival specimen bank (banked specimens not tied to specific trials)

B. Please indicate the approximate number:
  1. Number of independent protocols used for specimen collection
  Specimen collection depends on the following requirements:
  Tumor must be 2 cm in diameter or larger
  Tissue must resemble a malignant tumor macroscopically

  2. Total number of participants registered
  There are 6 registered participants, with different access level

    3. Total number of specimens banked
617 cases
    4. Annual specimen accrual
Around 200 cases
    5. Annual number of specimens distributed
Around 142 cases a year

C. Please indicate the type of specimens collected:
    1. Frozen Tissue Specimens
    2. Paraffin Blocks from Surgical Pathology Service (Physically Held)

D. Where are specimens collected:
    1. From a single site within the institution

E. What are the specimen / participant relationships:
    1. Multiple specimens collected from a single participant at multiple times

F. Where are specimens stored:
    1. In a single central location

G. Bank to Institution Relationships:
    1. Does the bank collect tissue for multiple medical/research institutions (more than one IRB, etc)

H. What associated clinical data is collected with each specimen?
    1. Donor Demographics
    2. Pathology Diagnosis and Findings
    3. Laboratory Data (Tumor Markers, etc) on Donor
    4. Therapy History of Donor
    5. Outcomes (Recurrence, Progression)
    6. Other

I. Are participants followed to update any of the clinical data below?
    1. Past or Future Pathology Reports
    2. Laboratory Data (Tumor Markers, etc)
    3. Clinical Status (Quality of Life)
    4. Outcomes (Recurrence, Progression)
    5. Vital Status
    6. Most recent follow up date

J. What is the immediate source of the clinical data collected?
    1. Pathology Reports
    2. Laboratory Reports
    3. Outcomes/Oncology Registries
    4. Medical Record

K. What Identifiers are stored with the specimen?

1. Tissue Bank "Accession" Number (Coded Number)
2. Surgical Pathology LIS Accession Number
3. Hospital Patient ID

IV.   Inter-Bank Relationships

A.   Please indicate data relationships between your specimen bank and other specimen banks with which you are aware.
1. This bank is stand-alone but could potentially interact with other relevant banks (e.g. similar organ site banks at other institutions or other organ site banks at the same institution)
2. This bank interacts using electronic data transfer with other banks (How many?) As part of the PCABC, this bank shares electronic data with other 5 institutions, also members of the Pennsylvania Cancer Alliance.

B.   If there is electronic data transfer between other banks, describe the nature of the data exchanged.
1. HIPAA De-identified Data
2. Demographic Data
3. Pathology Data
4. Outcomes Data

C.   If there are tissue samples exchanged between banks, describe the nature and circumstance of these transactions.

V.   Current Database System and Tools

Please circle all statements that apply.
A.   What is the current nature of your data system:
1. Multi-tiered database web server

B.   What modes of data entry do you currently utilize:
1. Manual entry of data
2. Manually merging of electronic data files

C.   What is the current disposition of your data system:
1. Adequate. Would replace it if something better was available

D.   How many Information Technology FTEs support the operation of your data system?   **5**

E.   How is metadata handled in the tissue bank:
1. Data definitions, Data Entry and Validation rules
Stored in database tables

VI.   System Access

A.   Please indicate methods in which users access your data system:

      1.   Through web-based intranet communication (single institution)

B.   Please indicate the types of users that access your system:
      1.   Bank personnel entering specimen tracking data
      2.   Administrators with read only / report access
      3.   Research investigators querying for specimens

C.   Do different users have levels of read permissions in your system?
Yes

D.   Do different users have levels of write (i.e data entry) permissions in your system?
Yes

E.   Does your system track user access to the system?
      1.   No

F.   Does your system log transactions:
      1.   There is no transaction logging

G.   Please describe any other unique access features of your system below:

VII.   IRB and Patient Confidentiality

A.   Under how many different IRB (Human Studies) protocols are specimens collected? If possible, please attach copies of these protocols and corresponding consent from language (as they pertain to specimen banking).
1 – see Appendix C.

B.   Does your IRB make provisions for banking specimens for future, unspecified research?
Yes

C.   Does your IRB make provision for aggregation and/or long term clinical follow up of tissue donors (participants).
Yes

D.   Are HIPAA-defined participant identifiers stored in your system?
Yes

E.   Are specimens ever distributed with HIPAA-defined participant identifiers?
No

F.   Are objects (i.e. participants or specimens) de-identified (coded) in your system? If so, explain the method of de-identification below:

They are coded with a tumor bank de-identified number

G.   Does your facility maintain an NCI-issued certificate of confidentiality?
No

H.   Are research results stored in your system?
No

I.   Please describe below the encryption / security measures utilized by your system to prevent access to participant identifiers:

J.   How would you rate your working relationship with your IRB:
    1.   **Good.** Regular communication with the IRB; No policy conflicts

K.   As much as possible, please briefly describe scenarios where the specimen bank has had policy conflicts with the IRB or where matters of patient confidentiality have been problematic.
None

L.   Who is responsible for the appropriate research use of banked tissue?
Juan Palazzo, MD.

VIII.   Distribution, Sharing, Material Transfer, and Intellectual Property (IP)

A.   Does the Bank work with Tissue Utilization Committees? (How many?)
No

B.   Who actually selects and approves the distribution of tissue to an investigator?
Dr. Juan Palazzo

C.   How are specimens "prioritized" for distribution in the tissue bank?
Based on the research merits, background of the investigator and number and type of specimens.

D.   How does your tissue bank measure investigator feedback?
We keep in constant contact with researchers receiving our tumors and seek their feedback regarding quality of the samples.

E.   How does the bank "market" itself and its tissue to investigators?
Participating in meetings, interacting with other researchers who have an interest in breast cancer research.

F.   Do you distribute specimens to extramural investigators who are named investigators on prospective collection studies?
No

G. Do you distribute specimens to extramural investigators who are not part of the original collection protocol or who are requesting specimens from your general specimen bank archive?

Yes

H. Do you have a standardized Materials Transfer Agreement for any specimen that is distributed extramurally? If so, please attach a copy of this agreement.

Yes – see Appendix D.

I. Do you distribute specimens to commercial entities?

Yes

J. How would you rate your working relationship with your Technology Transfer Office:

    1. **Good.** Standardized agreements available

K. As much as possible, please list key IP issues that have been raised at your institution with regard to sharing specimens and associated data with extramural institutions.

The confidentiality issues are paramount and we require IRB approved protocols from all participant researchers

L. Does your institution have an official policy on the release of pre-publication and post-publication data? If so, please describe:

No

IX. Data System Objects

For the purposes of this survey, 'Objects' are defined as physical entities about which data is collected and stored, usually in discrete data tables. Please indicate which objects are represented in your data system (note that the actual names of these objects may differ from system to system). In addition, please include your system's data schema.
Schema attached in Appendix A.

A. *Participants* (Donors): An individual from whom specimens are collected

B. *Admissions* (Tissue Collection Event): An event in time that results in one or more collected specimens from a participant

C. *Specimens*: Biological material that is collected from a participant

D. *Segments*: Aliquot or subdivision of a single collected specimen

E. *Users*: An individual who has access to the data system

X. **System Data Elements**

    A.   Please attach as **Appendix B**, a list of system data elements in the following format (This can be a dump of the table structures of a database):
        Table NameData Element NameData TypeControlled Values? Description

    B.   Please list any sources of common data elements or unified coding schemes employed by your system.

    C.   Does your system store other specialized data types (e.g. digital images)? Please specify and describe how they are used.
       No.

XI. **Use Cases**

Below is a list of representative use cases that may be commonly employed by a specimen banking data system. Please see section IX for definitions of representative objects. For each scenario, please indicate: 1=This functionality is not needed in the system; 2=This functionality is currently not employed in the system, but would be desirable; 3=This functionality is absolutely essential for the system.

    A.   Data Entry
        1. Register a new user **(3)**
        2. Participant data
            a. Register a new participant to a study
            b. Enter new clinical data on existing participant
        3. Admission data **(3)**
            a. Enter pathology data for admission
        4. Specimen data **(3)**
            a. Register a new specimen for a new admission
            b. Register a new specimen for an existing admission
        5. Please list other specific data entry tasks required / desired for your system below:

    B.   Data Update
        1. Participant data **(3)**
            a. Update participant demographics
            b. Update participant clinical data
        2. Admission data **(3)**
            a. Update pathology data for admission
        3. Specimen data **(3)**
            a. Update specimen location
            b. Update specimen status (available, accessed, processed, etc.)
            c. Register specimen distribution (linked to create specimen distribution)
        4. Sample data **(3)**

      a. Update sample location
      b. Update sample status
      c. Register sample distribution (linked to create sample distribution)

5. Please list other specific data update tasks required / desired for your system below:

C. Data Querying **(3 for all)**
1. Query for specimens / samples by study
2. Query for specimens / samples by collection site
3. Query for specimens / samples by participant
4. Query for specimens / samples by Clinical / Pathological criteria
5. Query for specimens / samples by specimen attribute
6. Query for specimens / samples by research data
7. Query for specimens / samples by investigator use
8. Please list other specific data query tasks required / desired for your system below:

D. Other
1. Please list other specific tasks required / desired for your system below:

XII.   **The caBIG Virtual Specimen Repository**

One potential goal of the caBIG initiative is to create a virtual specimen repository where institutions could exchange specimen inventory data, actual biospecimens, and research data generated from such specimens.

A. Is your bank part of such a multi-institutional virtual tissue bank today?
It's in the process of becoming one.

B. Below, please indicate whether any of the following issues will impede the progress toward this goal at your institution (1=significantly prevent, 2=may prevent, 3=can be resolved, 4=will not impede):

1. IRB / Human Studies concerns about sharing specimen data (e.g. creating a web-accessible specimen catalog)
4

2. IRB / Human Studies concerns about sharing specimens with other investigators for research studies not initially presented in the collection protocol / consent form

4

3. IP concerns about sharing specimens with extramural institutions
3

4. IP concerns about sharing research data generated from shared specimens
3

5. Competing scientific interests for use of specimens
3

6. Limited Information Systems support to create the required interfaces for inter-institutional data systems communication
3

7. Perceived loss of control of specimens/data
4

8. Please list below other specific restrictions that may limit the ability to share biospecimens and biospecimen data at your institution:

Appendix A. Please attach your system's data schema

Appendix B. Please attach a list of your system's data elements

Appendix C. Please attach language utilized by IRB protocols and consent form documents associated with specimen collection and banking

Appendix D. Please attach any standardized Materials Transfer Agreement utilized by your bank

Appendix E. Please attach examples of any administrative or client reports generated by your bank

XIII. FREE TEXT SECTION

A. Please provide a diagram identifying the main stakeholders in the tissue bank (IRB, Sponsoring Projects, Research Projects, Tissue Donors etc.) and their relationships between each other and the tissue bank.

B. Please provide a free text description of how the following activities occur in the tissue bank:

1. How is a typical Specimen Accessioned?

Specimens are received in the Pathology Department with a central accession Hospital number. They're grossed (which includes dissection and dictation) and after a tumor is identified and selected for pathologic diagnosis, if it is 2 cm or larger, a representative section is procured for the tumor bank.
Tissue is frozen in liquid nitrogen and submitted into -70° degree freezer until final pathologic diagnosis is made. The tissue is then submitted into the bank which is kept at -150°.
Pathology Reports are then entered into database which gives a sequential number to the case. Patient's data is entered and stored with a tumor bank number de-identifying the patients.

2. How does an investigator request tissue from the bank and how does that request become a formal order and an actual distribution?

All requests must be submitted to Dr. Palazzo. Depending on the type of research and the characteristics of the tissue requested and the availability of an adequate number of specimens, tissue samples can be provided along with de-identified case information.
Tissue is removed from -150° bank – into dry ice and is shipped FedEx overnight to recipient.
The tissue is identified with our tumor bank number only.

3. How does the bank Q/A its inventory?

Q/A of inventory is done by hard copy of pathology reports and random inquiries.

APPENDIX A:

KIMMEL CANCER CENTER (JEFFERSON) BREAST TISSUE DATABASE SCHEMA.

PERSONAL HISTORY	OTHER MEDICAL HISTORY	FAMILY HISTORY
STUDYNUMBER	STUDYNUMBER	STUDYNUMBER

MENSTRUAL / REPRODUCTIVE HISTORY	LIFESTYLE
STUDYNUMBER	STUDYNUMBER

REGISTRATION DATA

STUDYNUMBER

BREAST HISTORY
STUDYNUMBER

SURGICAL PATHOLOGY DATA	TUMOR BANK DATA
STUDYNUMBER	SURGPATH NUMBER
SURGPATH NUMBER	
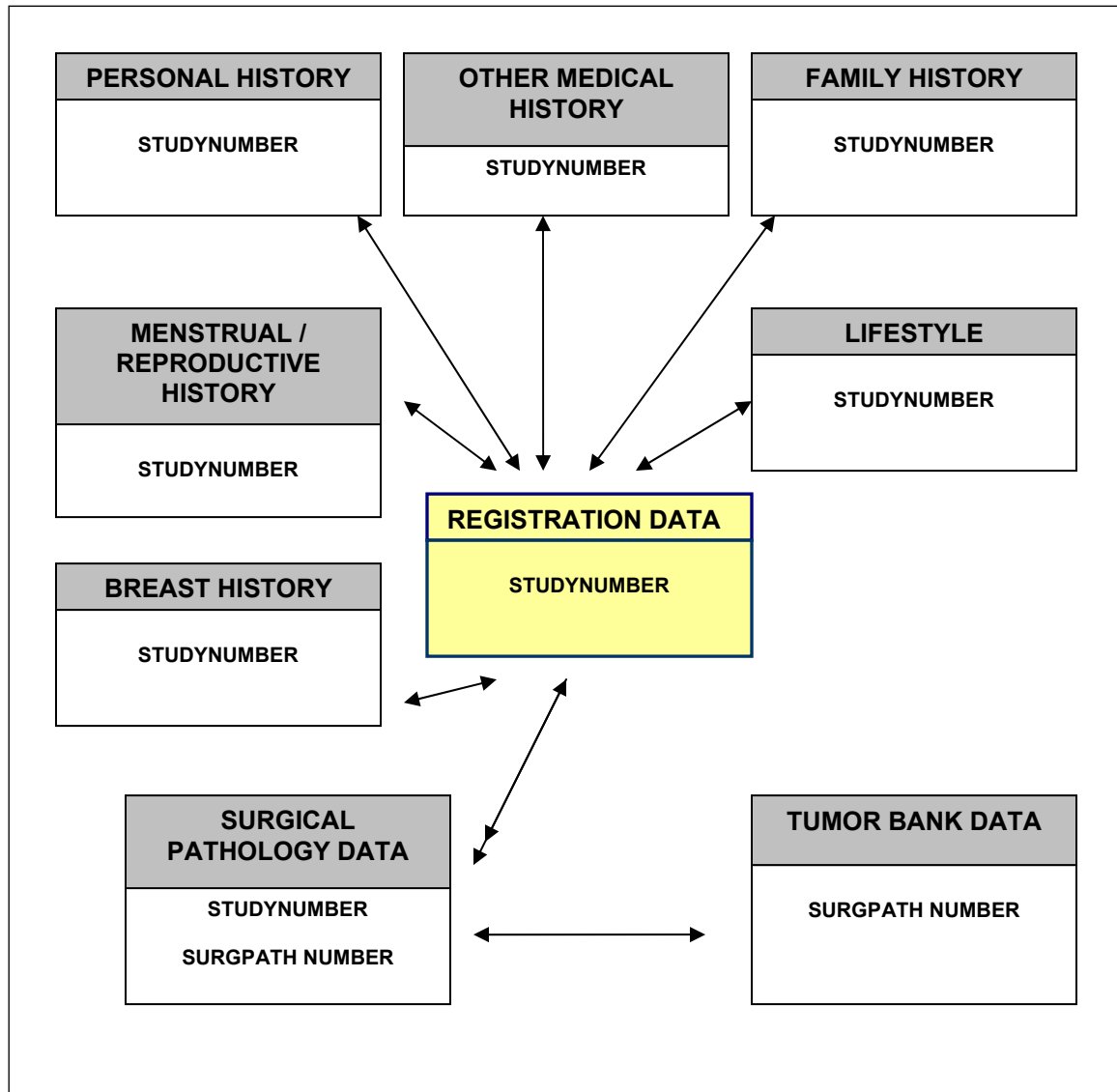
KIMMEL CANCER CENTER (JEFFERSON) BREAST TISSUE DATABASE SYSTEM DATA ELEMENTS.

REGISTRATION DATA TABLE

DataElement	DataLabel	DataType	DataFieldLength	Valid Value 1	Valid Value 2	Valid Value 3	Valid Value 4	Valid Value 5	Valid Value 6	Valid Value 7	Valid Value 8	Valid Value 9	Valid Value 10	Valid Value 11	Valid Value 12	Valid Value 13	Valid Value 14	Valid Value 15	Valid Value 16	Valid Value 17	Valid Value 18	Valid Value 19	Valid Value 20
MRnumber	MR #	varchar	15																				
LastName	Last Name	varchar	15																				
FirstName	First Name	varchar	15																				
Gender	Gender	varchar	6	Female	Male																		
StreetAddress	Street Address	varchar	30																				
City	City	varchar	30																				
State	State	varchar	2																				
Zip	Zip	varchar	10																				
TelephoneHome	Telephone (Home)	varchar	14																				
TelephoneWork	Telephone (Work)	varchar	14																				
SSN	Soc Sec #	varchar	10																				
Occupation	Occupation	varchar	30																				
Insurance	Insurance	varchar	30																				
InsIDnum	Insurance ID#	varchar	20																				
ReferPhysician	Referring Physician	varchar	30	Anne Rosenberg	Donna Barbot	Edith Mitchell	Edward Sauter	Ernest Rosato	Francis Rosato	Gordon Schwartz	Herbert Cohn	James Fox	Jennifer Sabol	John Moore	Kris Kaulback	Marvin A. Krane	Melvin Moses	Michael Weinstein	Paul Curcillo	Pauline Park	Robert McCairns	Stephanie King	Steven Copit
ReferPhysPhone	Referring Physician Telephone	varchar	14																				
PrimaryPhysician	Primary Care Physician	varchar	30																				
PrimPhysPhone	Primary Care Physician Telephone	varchar	14																				
Gynecologist	Gynecologist	varchar	30																				
GynePhone	Gynecologist Telephone	varchar	14																				

SURGICAL PATHOLOGY DATA TABLE

DataElement	DataLabel	DataType	DataFieldLength	Valid Value 1	Valid Value 2	Valid Value 3	Valid Value 4	Valid Value 5	Valid Value 6	Valid Value 7	Valid Value 8	Valid Value 9	Valid Value 10	Valid Value 11	Valid Value 12	Valid Value 13	Valid Value 14	Valid Value 15	Valid Value 16	Valid Value 17	Valid Value 18	Valid Value 19	Valid Value 20
SurgPathNum	Surgical Pathology Number (A01-12345)	varchar	10																				
AccDate	Accession Date (mm/dd/yyyy)	varchar	10																				
SpecType	Specimen Type	varchar	35	Needle core biopsy	Lumpectomy w/o margins	Lumpectomy w/ margins	Lumpectomy w/ separate margins	Re-excisional biopsy	Simple mastectomy	Modified radical mastectomy	Radical mastectomy	Reduction mammoplasty	Other										
TumorBank	Tumor Bank	varchar	3	yes	no																		
SiteLesion	Site of Lesion	varchar	30	Left - Upper Inner Quadrant	Left - Upper Outer Quadrant	Left - Lower Inner Quadrant	Left - Lower Outer Quadrant	Right - Upper Inner Quadrant	Right - Upper Outer Quadrant	Right - Lower Inner Quadrant	Right - Lower Outer Quadrant	Bilateral - Upper Inner Quadrant	Bilateral - Upper Outer Quadrant	Bilateral - Lower Inner Quadrant	Bilateral - Lower Outer Quadrant	Left - Quadrant NOT SPECIFIED	Right - Quadrant NOT SPECIFIED						
LNexcision	Lymph Node excision	varchar	3	yes	no																		
TypeLNexcision	Type of Lymph Node excision	varchar	60	Sentinel node biopsy	Axillary lymph node dissection w/o designated leve	Axillary lymph node dissection w/ designated level																	
BreastPathTag	Breast Pathology	varchar	80																				
BenignNonNeoTag	Benign Non-Neoplastic	varchar	80	Fibrocystic changes NOS	Ductal hyperplasia w/o atypia (proliferative fibro	Sclerosing adenosis	Microglandular adenosis	Adenosis NOS	Stromal fibrosis (fibrous mastopathy)	Duct ectasia	Fat necrosis	Diabetic mastopathy	Papillomatosis	Intra ductal papilloma	Collagenous spherulosis	Radial scar (sclerosing lesion)	Chemotherapy/ radiation effect	Fibromatosis	Pseudo angiomatoid hyperplasia	Normal			
BenignNonNeo01	1. Fibrocystic changes NOS	varchar	1																				
BenignNonNeo02	2. Ductal hyperplasia w/o atypia (proliferative fibro	varchar	1																				
BenignNonNeo03	3. Sclerosing adenosis	varchar	1																				
BenignNonNeo04	4. Microglandular adenosis	varchar	1																				
BenignNonNeo05	5. Adenosis NOS	varchar	1																				
BenignNonNeo06	6. Stromal fibrosis (fibrous mastopathy)	varchar	1																				
BenignNonNeo07	7. Duct ectasia	varchar	1																				
BenignNonNeo08	8. Fat necrosis	varchar	1																				
BenignNonNeo09	9. Diabetic mastopathy	varchar	1																				
BenignNonNeo10	10. Papillomatosis	varchar	1																				
BenignNonNeo11	11. Intra ductal papilloma	varchar	1																				
BenignNonNeo12	12. Collagenous spherulosis	varchar	1																				
BenignNonNeo13	13. Radial scar (sclerosing lesion)	varchar	1																				
BenignNonNeo14	14. Chemotherapy/ radiation effect	varchar	1																				
BenignNonNeo15	15. Fibromatosis	varchar	1																				
BenignNonNeo16	16. Pseudo angiomatoid hyperplasia	varchar	1																				
BenignNonNeo17	17. Normal	varchar	1																				
BenignNeoTag	Benign Neoplastic	varchar	80	Fibroadenoma (NOS)	Hemangioma	Fibroadenoma w/ ductal hyperplasia	Breast hamartoma	Tubular adenoma	Myoepithelial tumor	Phylloides tumor	Granular cell tumor												
BenignNeo01	1. Fibroadenoma (NOS)	varchar	1																				
BenignNeo02	2. Hemangioma	varchar	1																				
BenignNeo03	3. Fibroadenoma w/ ductal hyperplasia	varchar	1																				
BenignNeo04	4. Breast hamartoma	varchar	1																				
BenignNeo05	5. Tubular adenoma	varchar	1																				
BenignNeo06	6. Myoepithelial tumor	varchar	1																				
BenignNeo07	7. Phylloides tumor	varchar	1																				
BenignNeo08	8. Granular cell tumor	varchar	1																				
BorderlineTag	Borderline	varchar	80	Ductal hyperplasia w/ atypia	Atypical lobular hyperplasia	Atypical papilloma																	
Borderline01	1. Ductal hyperplasia w/ atypia	varchar	1																				
Borderline02	2. Atypical lobular hyperplasia	varchar	1																				
Borderline03	3. Atypical papilloma	varchar	1																				
MaligEpithTag	Malignant Epithelial	varchar	80	DCIS	DCIS w/ microinvasion	LCIS	Papillary carcinoma	Invasive ductal carcinoma (in situ/invasive/ NOS)	Invasive lobular carcinoma	Mixed carcinoma (ductal/ lobular)	Metastatic from contralateral breast												
MaligEpith01	1. DCIS	varchar	1																				
MaligEpith02	2. DCIS w/ microinvasion	varchar	1																				
MaligEpith03	3. LCIS	varchar	1																				
MaligEpith04	4. Papillary carcinoma	varchar	1																				
MaligEpith05	5. Invasive ductal carcinoma (in situ/invasive/ NOS)	varchar	1																				
MaligEpith06	6. Invasive lobular carcinoma	varchar	1																				
MaligEpith07	7. Mixed carcinoma (ductal/ lobular)	varchar	1																				
MaligEpith08	8. Metastatic from contralateral breast	varchar	1																				
MaligOtherTag	Malignant Other	varchar	80	Malignant phylloides tumor	Primary breast lymphoma NOS	Primary breast sarcoma NOS	Metastasis from other site	Other															
MaligOther01	1. Malignant phylloides tumor	varchar	1																				
MaligOther02	2. Primary breast lymphoma NOS	varchar	1																				
MaligOther03	3. Primary breast sarcoma NOS	varchar	1																				

DataElement	DataLabel	DataType	DataFieldLength	Valid Value 1	Valid Value 2	Valid Value 3	Valid Value 4	Valid Value 5	Valid Value 6	Valid Value 7	Valid Value 8	Valid Value 9	Valid Value 10	Valid Value 11	Valid Value 12	Valid Value 13
MaligOther04	4. Metastasis from other site	varchar	1													
MaligOther05	5. Other	varchar	1													
SubDCIS	Subtype of DCIS	varchar	20	Cribriform	Solid	Micropapillary	Clinging	Comedo	Mixed	N/A						
SubInv	Subtype of Invasive Component	varchar	20	Tubular	Medullary	Colloid	Papillary	Metaplastic	Mucinous	Apocrine	Secretory	Adenoidcystic	Cribriform	Clear cell	Other	N/A
OtherFeatures	Other Features	varchar	35	Inflammatory carcinoma	Pagets disease	Pagetoid spread	Involving sclerosing adenosis									
TumorSize	Tumor Size (in cm or N/A)	varchar	10													
TumorNucGrade	Tumor Nuclear Grade (use highest grade)	varchar	80	I	II	III										
HistGrade	Histologic Grade (use highest grade)	varchar	80	I	II	III										
NumPosMargins	Number of Positive Margins (or N/A)	varchar	3													
DistMargin	Closest Distance to Margin (in cm or N/A)	varchar	5													
VascSpace	Vascular Space Involvement	varchar	20	Negative	Positive	Positive extensive	N/A									
LNTag	Lymph Nodes Assessment	varchar	80													
NumSampledLN	Number of sampled lymph nodes	varchar	2													
NumPosLN	Number of positive lymph nodes	varchar	2													
NumLNL1	Number of lymph nodes level I (or N/A)	varchar	3													
NumPosLNL1	Number of positive lymph nodes level I (or N/A)	varchar	3													
NumLNL2	Number of lymph nodes level II (or N/A)	varchar	3													
NumPosLNL2	Number of positive lymph nodes level II (or N/A)	varchar	3													
NumLNL3	Number of lymph nodes level III (or N/A)	varchar	3													
NumPosLNL3	Number of positive lymph nodes level III (or N/A)	varchar	3													
LargestTumLN	Largest tumoral lymph node (in cm or N/A)	varchar	5													
ExtranodalExt	Extranodal extension	varchar	3	yes	no											
SNTag	Sentinel Nodes	varchar	80													
NumSN	Number sampled Sentinel Nodes	varchar	2													
SNhist	Histological assessment	varchar	8	Positive	Negative											
SNimmuno	Immunohistochemistry assessment	varchar	8	Positive	Negative											
ImmunoPanelTag	Breast Immunohistochemistry Panel	varchar	80													
IPER	ER: % of tumoral cells (or N/A)	varchar	3													
IPPR	PR: % of tumoral cells (or N/A)	varchar	3													
IPki67	Ki67 (proliferation marker): % of tumoral cells (or N/A)	varchar	3													
IPp21	P21: % of tumoral cells (or N/A)	varchar	3													
IPp53	P53: % of tumoral cells (or N/A)	varchar	3													
IPcerb2	C-erb2: % of tumoral cells / Weak/ Moderate/ Strong (or N/A)	varchar	8													
IPHercep	Herceptest	varchar	8	Positive	Negative											

TUMOR BANK DATA TABLE

DataElement	DataLabel	DataType	DataFieldLength	Valid Value 1	Valid Value 2	Valid Value 3	Valid Value 4	Valid Value 5	Valid Value 6	Valid Value 7	Valid Value 8	Valid Value 9	Valid Value 10	Valid Value 11	Valid Value 12	Valid Value 13	Valid Value 14	Valid Value 15	Valid Value 16	Valid Value 17	Valid Value 18	Valid Value 19	Valid Value 20
TumorBankTag	Tumor Bank Data	varchar	80																				
BreastBankNum	Breast Bank Number	varchar	4																				
BoxLocation	Box Location (000-00)	varchar	6																				
SurgPathNum	Surgical Pathology Number	varchar	10																				
TumorTissueSamples	Tumor Tissue Samples	varchar	2																				
NormalTissueSamples	Normal Tissue Samples	varchar	2																				
TumorTouchPreps	Tumor Touch Preps	varchar	2																				
NormalTouchPreps	Normal Touch Preps	varchar	2																				
TumorParaffinBlocks	Tumor Paraffin Blocks	varchar	2																				
NormalParaffinBlocks	Normal Paraffin Blocks	varchar	2																				
MetTumorLN	Metastatic Tumor to Lymph Node	varchar	2																				
MetTumorOther	Metastatic Tumor to Other Sites	varchar	2																				
LNmetParaffinBlocks	LN Met Paraffin Blocks	varchar	2																				
OTHERmetParaffinBlocks	Other Site Met Paraffin Blocks	varchar	2																				
SpecimensUsedTag	Specimens Used	varchar	80																				
1stRequestTag	1st Request	varchar	80																				
ReqestNum1	1st Request Number	varchar	4																				
TumorTissue1	1st Request Tissue Samples	varchar	2																				
NormalTissue1	1st Request Normal Samples	varchar	2																				
TumorTouch1	1st Request Tumor Touch Preps	varchar	2																				
NormalTouch1	1st Request Normal Touch Preps	varchar	2																				
TumorParaffin1	1st Request Tumor Paraffin Slides	varchar	2																				
NormalParaffin1	1st Request Normal Paraffin Slides	varchar	2																				
LNMet1	1st Request LN Met Tissue	varchar	2																				
Met1	1st Request Met Tissue	varchar	2																				
LNmetParaffin1	1st Request LN Met Paraffin Slides	varchar	2																				
MetParaffin1	1st Request Met Paraffin Slides	varchar	2																				
2ndRequestTag	2nd Request	varchar	80																				
ReqestNum2	2nd Request Number	varchar	4																				
TumorTissue2	2nd Request Tissue Samples	varchar	2																				
NormalTissue2	2nd Request Normal Samples	varchar	2																				
TumorTouch2	2nd Request Tumor Touch Preps	varchar	2																				
NormalTouch2	2nd Request Normal Touch Preps	varchar	2																				
TumorParaffin2	2nd Request Tumor Paraffin Slides	varchar	2																				
NormalParaffin2	2nd Request Normal Paraffin Slides	varchar	2																				
LNMet2	2nd Request LN Met Tissue	varchar	2																				
Met2	2nd Request Met Tissue	varchar	2																				
LNmetParaffin2	2nd Request LN Met Paraffin Slides	varchar	2																				
MetParaffin2	2nd Request Met Paraffin Slides	varchar	2																				
3rdRequestTag	3rd Request	varchar	80																				
ReqestNum3	3rd Request Number	varchar	4																				
TumorTissue3	3rd Request Tissue Samples	varchar	2																				
NormalTissue3	3rd Request Normal Samples	varchar	2																				
TumorTouch3	3rd Request Tumor Touch Preps	varchar	2																				
NormalTouch3	3rd Request Normal Touch Preps	varchar	2																				
TumorParaffin3	3rd Request Tumor Paraffin Slides	varchar	2																				
NormalParaffin3	3rd Request Normal Paraffin Slides	varchar	2																				
LNMet3	3rd Request LN Met Tissue	varchar	2																				
Met3	3rd Request Met Tissue	varchar	2																				
LNmetParaffin3	3rd Request LN Met Paraffin Slides	varchar	2																				
MetParaffin3	3rd Request Met Paraffin Slides	varchar	2																				
4thRequestTag	4th Request	varchar	80																				
ReqestNum4	4th Request Number	varchar	4																				
TumorTissue4	4th Request Tissue Samples	varchar	2																				
NormalTissue4	4th Request Normal Samples	varchar	2																				
TumorTouch4	4th Request Tumor Touch Preps	varchar	2																				
NormalTouch4	4th Request Normal Touch Preps	varchar	2																				
TumorParaffin4	4th Request Tumor Paraffin Slides	varchar	2																				
NormalParaffin4	4th Request Normal Paraffin Slides	varchar	2																				
LNMet4	4th Request LN Met Tissue	varchar	2																				
Met4	4th Request Met Tissue	varchar	2																				
LNmetParaffin4	4th Request LN Met Paraffin Slides	varchar	2																				
MetParaffin4	4th Request Met Paraffin Slides	varchar	2																				
5thRequestTag	5th Request	varchar	80																				

DataElement	DataLabel	DataType	DataFieldLength
ReqestNum5	5th Request Number	varchar	4
TumorTissue5	5th Request Tissue Samples	varchar	2
NormalTissue5	5th Request Normal Samples	varchar	2
TumorTouch5	5th Request Tumor Touch Preps	varchar	2
NormalTouch5	5th Request Normal Touch Preps	varchar	2
TumorParaffin5	5th Request Tumor Paraffin Slides	varchar	2
NormalParaffin5	5th Request Normal Paraffin Slides	varchar	2
LNMet5	5th Request LN Met Tissue	varchar	2
Met5	5th Request Met Tissue	varchar	2
LNmetParaffin5	5th Request LN Met Paraffin Slides	varchar	2
MetParaffin5	5th Request Met Paraffin Slides	varchar	2

BREAST HISTORY TABLE

DataElement	DataLabel	DataType	DataFieldLength	Valid Value 1	Valid Value 2	Valid Value 3	Valid Value 4	Valid Value 5
BreastHistoryTag	Breast History Information	varchar	80					
SelfExam	Do you practice breast self-examination?	varchar	40	No, never	Yes, rarely	Yes, when I remember to do so	Yes, regularly, but not every month	Every month
Lump	Do you think you have a breast lump? (If yes, which breast?)	varchar	20	No	Yes, LEFT breast	Yes, RIGHT breast		
OtherProblems	Other breast problems (please describe)	varchar	40					
MammogramLast	When was your last mammogram?	varchar	30	Never had one	Within the past 6 months	6 to 12 months ago	1 to 2 years ago	2 to 5 years ago	more than 5 years ago
MammogramAbnormal	If your last mammogram was abnormal, enter the month / year	varchar	10					
Ultrasound	If you have had a breast ultrasound, enter the month / year	varchar	10					
Biopsy	Have you ever had breast surgery (biopsy)?	varchar	30	No	Yes, once - left breast	Yes, once - right breast	Yes, more than once - left breast	Yes, more than once - right breast
BiopsyDates	If you have had surgery (biopsy), list the dates (month/year) separated by comma	varchar	40					
HadBreastCancer	Do (did) you have breast cancer?	varchar	20	No	Do not know	Yes, left breast	Yes, right breast	
YearBreastCancer	If you have (had) breast cancer, what year where you first diagnosed?	varchar	4					
BraSize	What is your bra size (for example, 34-B)?	varchar	5					
Discomfort	Do (did) your breasts bother you before menstrual periods?	varchar	15	Never	Rarely	Occasionally	Frequently	Almost always

FAMILY HISTORY TABLE

DataElement	DataLabel	DataType	DataFieldLength	Valid Value 1	Valid Value 2	Valid Value 3	Valid Value 4	Valid Value 5	Valid Value 6	Valid Value 7	Valid Value 8	Valid Value 9	Valid Value 10	Valid Value 11	Valid Value 12	Valid Value 13
FamilyHistoryTag	Family History of Cancer	varchar	80													
MotherBC	Does (did) your mother have breast cancer?	varchar	30	No	Yes, before her menopause	Yes, after her menopause	Yes, in both breasts	Do not know								
Sisters	Do (did) you have sisters?	varchar	80	No	1	2	3	4	5	6	7	8	9	10	more	unknown
SistersBirthYears	Years of birth of sisters (separate by commas)	varchar	40													
Brothers	Do (did) you have brothers?	varchar	80	No	1	2	3	4	5	6	7	8	9	10	more	unknown
BrothersBirthYears	Years of birth of brothers (separate by commas)	varchar	40													
SistersBC	Do (did) any of your sisters have breast cancer?	varchar	30	No	Yes, before menopause	Yes, after menopause										
GrandmothersBC	Does (did) either of your grandmothers have breast cancer?	varchar	50	No	Yes, mother's mother, before menopause	Yes, mother's mother, after menopause	Yes, father's mother, before menopause	Yes, father's mother, after menopause								
AuntBC	Does (did) any aunt have breast cancer?	varchar	50	No	Yes, mother's side, before menopause	Yes, mother's side, after menopause	Yes, father's side, before menopause	Yes, father's side, after menopause								
CousinBC	Does (did) any first cousin have breast cancer?	varchar	50	No	Yes, mother's side, before menopause	Yes, mother's side, after menopause	Yes, father's side, before menopause	Yes, father's side, after menopause								
MaleBC	Specify (brother, uncle, father, etc.) any MALE relatives with breast cancer	varchar	50													
MedicationsTag	Summarize all cases of ANY cancer in your immediate family	varchar	80													
Relation1	Relationship to you #1	varchar	20													
AgeDx1	Age at diagnosis #1	varchar	2													
Alive1	Alive? #1	varchar	3	yes	no											
AgeDeath1	Age at death #1	varchar	2													
Dx1	Type of cancer #1	varchar	30													
Relation2	Relationship to you #2	varchar	20													
AgeDx2	Age at diagnosis #2	varchar	20													
Alive2	Alive? #2	varchar	3	yes	no											
AgeDeath2	Age at death #2	varchar	2													
Dx2	Type of cancer #2	varchar	30													
Relation3	Relationship to you #3	varchar	20													
AgeDx3	Age at diagnosis #3	varchar	2													
Alive3	Alive? #3	varchar	3	yes	no											
AgeDeath3	Age at death #3	varchar	2													
Dx3	Type of cancer #3	varchar	30													
Relation4	Relationship to you #4	varchar	20													
AgeDx4	Age at diagnosis #4	varchar	2													
Alive4	Alive? #4	varchar	3	yes	no											
AgeDeath4	Age at death #4	varchar	2													
Dx4	Type of cancer #4	varchar	30													
Relation5	Relationship to you #5	varchar	20													
AgeDx5	Age at diagnosis #5	varchar	2													
Alive5	Alive? #5	varchar	3	yes	no											
AgeDeath5	Age at death #5	varchar	2													
Dx5	Type of cancer #5	varchar	30													

LIFESTYLE TABLE

DataElement	DataLabel	DataType	DataFieldLength	Valid Value 1	Valid Value 2	Valid Value 3	Valid Value 4
LifestyleTag	Lifestyle	varchar	80				
Tobacco	Do (did) you use tobacco?	varchar	20	No	Cigarettes	Cigars	Chewing tobacco
TobaccoQuantity	What quantity of tobacco per day?	varchar	15				
TobaccoYears	How many years have (had) you used tobacco?	varchar	2				
Alcohol	Do (did) you drink alcohol?	varchar	20	No	Wine	Beer	Hard Liquor	Other
AlcoholQuantity	How much alcohol (drinks) per day	varchar	15				
AlcoholYears	How many years have (had) you drank alcohol?	varchar	2				

DataElement	DataLabel	DataType	DataFieldLength	Valid Value 1	Valid Value 2	Valid Value 3	Valid Value 4	Valid Value 5
Exercise	Do you exercise regularly?	varchar	25	No	Daily	2 to 3 times a week	Once a week	Less than once a week
Diet	Do you eat a special diet?	varchar	25	No	Vegetarian	Vegan	Kosher	Other

MENSTRUAL HISTORY TABLE

DataElement	DataLabel	DataType	DataFieldLength	Valid Value 1	Valid Value 2	Valid Value 3	Valid Value 4	Valid Value 5	Valid Value 6	Valid Value 7	Valid Value 8	Valid Value 9	Valid Value 10	Valid Value 11	Valid Value 12	Valid Value 13	Valid Value 14	Valid Value 15	Valid Value 16	Valid Value 17	Valid Value 18	Valid Value 19	Valid Value 20
MenstrualHistoryTag	Menstrual & Reproductive History Information	varchar	80																				
Age1stPeriod	Age at 1st menstrual period?	varchar	2																				
NumPregnancies	How many times have you been pregnant?	varchar	4	0	1	2	3	4	5	6	7	8	9	10	more								
NumComplete	How many complete preganancies	varchar	4	0	1	2	3	4	5	6	7	8	9	10	more								
Age1stPregnancy	Age when you first became pregnant?	varchar	2																				
AgeLastPregnancy	Age when you last (most recently) became pregnant?	varchar	2																				
MiscarriageAbortion	Have you ever had a miscarriage or abortion, voluntary or accidental?	varchar	25	No	Yes, once	Yes, more than once																	
AgesMiscAbort	If you have had a miscarriage(s) or abortion(s), list year(s) or age(s)	varchar	30																				
Nurse	Did you nurse any of your children?	varchar	3	No	Yes																		
MonthsNursed	If you have nursed, total months for all children?	varchar	2																				
AgesGendersChildren	Ages and genders of your children? (example: M-3,F-5,M10)	varchar	40																				
Periods	Are you still having menstrual periods?	varchar	20	No	Yes, Regular	Yes, Irregular																	
DateLastPeriod	Date (month/day/4-digit year) of your last menstrual period?	varchar	10																				
AgeFinalPeriod	If you are no longer having periods, at what age did you have your last?	varchar	2																				
Reason	If you are no longer having periods, why?	varchar	30	Natural Menopause	Operation	Chemotherapy	Tamoxifen / Hormones	Other															
Ovaries	If you had an operation that stopped your periods, were your ovaries also remove	varchar	25	No	Both ovaries removed	One ovary removed	Not sure																
Hormones	Are you taking any female hormones at this time?	varchar	40	None	Birth control pills	Estrogen replacement	Estrogen AND progesterone	Estrogen vaginal cream or ring	Other														
PastHormones	Have you EVER taken female hormones?	varchar	40	None	Birth control pills	Fertility drugs	Hormones during pregnancy	Estrogen replacement	Estrogen AND progesterone	Estrogen vaginal cream or ring	Other												
BirthControlPills	Length of time you have taken birth control pills?	varchar	25	Never	Less than 6 months	6 to 12 months	1 to 2 years	2 to 5 years	5 to 10 years	longer than 10 years													
PillNames	Name(s) of birth control pills you have taken (current, previous, etc.)?	varchar	40																				
Estrogens	How long have you taken estrogens for menopausal symptoms?	varchar	25	Never	Less than 6 months	6 to 12 months	1 to 2 years	2 to 5 years	5 to 10 years	longer than 10 years													
LastHormone	When did you last take female hormones (estrogens or birth control pills)?	varchar	30	Never did	Within the past 30 days	1 to 6 months ago	6 to 12 months ago	More than 1 year ago															

OTHER MEDICAL HISTORY TABLE

DataElement	DataLabel	DataType	DataFieldLength	Valid Value 1	Valid Value 2	Valid Value 3	Valid Value 4	Valid Value 5	Valid Value 6	Valid Value 7	Valid Value 8	Valid Value 9	Valid Value 10	Valid Value 11	Valid Value 12	Valid Value 13	Valid Value 14	Valid Value 15	Valid Value 16	Valid Value 17	Valid Value 18	Valid Value 19	Valid Value 20
OtherMedicalHistoryTag	Other Medical History	varchar	80																				
OtherProblems	Describe any OTHER health problems	varchar	80																				
MajorSurgery	Describe any major surgical operations you have had	varchar	80																				
Allergies	Describe any allergies you have to medications, foods, or other products	varchar	80																				
MedicationsTag	List the NAME, DOSE, TIMES/DAY, and REASON for any medicine you regularly take	varchar	80																				
Meds1	medication #1	varchar	80																				
Meds2	medication #2	varchar	80																				
Meds3	medication #3	varchar	80																				
Meds4	medication #4	varchar	80																				

PERSONAL HISTORY TABLE

DataElement	DataLabel	DataType	DataFieldLength	Valid Value 1	Valid Value 2	Valid Value 3	Valid Value 4	Valid Value 5	Valid Value 6	Valid Value 7	Valid Value 8	Valid Value 9	Valid Value 10	Valid Value 11	Valid Value 12	Valid Value 13	Valid Value 14	Valid Value 15	Valid Value 16	Valid Value 17	Valid Value 18	Valid Value 19	Valid Value 20
PatientHistoryTag	Personal History Information	varchar	80																				
MaritalStatus	Marital Status	varchar	30	Married (once only)	Single - never married	Divorced or separated	Divorced & remarried	Widowed	Widowed & remarried														
Race	Race	varchar	50	American Indian or Alaska Native	Asian	Black or African American	Native Hawaiian or Other Pacific Islander	White															
Ethnicity	Ethnicity	varchar	50	Hispanic or Latino	Not Hispanic or Latino																		
Religion	Religion (by birth, not which religion you practice now)	varchar	30	Catholic	Protestant (any denomination)	Ashkenazi	Muslim	Hindu	Buddhist	Other													
BirthDate	Birth Date (month / day / 4-digit year)	varchar	10																				
BirthLocation	Where were you born? (In US, 2-letter state abbr -- otherwise, country)	varchar	30																				
YearsUSA	If born outside the US, how long (years) have you lived IN the US	varchar	2																				
Education	Your highest level of education	varchar	30	Grade 1-8	Grade 9-11	Graduated high school	Some college or professional school	College graduate	Beyond college														
VisitReason	Reason for your visit today	varchar	40	Routine check-up	I found something I want checked	My doctor found something	Surgical oncology opinion	Medical oncology opinion	Radiation therapy opinion	Reconstructive surgery opinion	Genetic counseling												

APPENDIX C:

1. SUMMARY OF HUMAN SUBJECTS RESEARCH PROTOCOL

2. REQUEST FOR WAIVER OF INFORMED CONSENT/ AUTHORIZATON TO COLLECT PROTECTED HEALTH INFORMATION

3. Continuing or Final Review of Research Protocols Involving Human Subjects

Thomas Jefferson University—Division of Human Subjects Protection

SUMMARY OF HUMAN SUBJECTS RESEARCH PROTOCOL

Please address all applicable points to create a complete and succinct synopsis of the protocol. Use language, insofar as is possible, that can be understood by an external, non-scientist layperson, and provide meanings for all acronyms used. **Form must be typewritten.**

(Maintain subheadings in body of text.)

1. Introduction and rationale for study

The Department of Pathology at Thomas Jefferson University Hospital (TJUH) processes approximately 2000 diagnositic breast samples a year. These samples are examples of benign and malignant breast diseases obtained from patients that undergo surgical biopsies and resections at TJUH. These tissues are used for diagnostic purposes, but frequently there is additional tissue not used for diagnosis. In order to maximize the yield of information obtained from these tissues, we propose creating a tissue depository and a tissue banking information system for breast samples to be able to make them available for research studies.

2. Specific aim(s)
a. Keep a depository of fresh forzen breast samples.
b. Comprehensive database with Pathology and Clinical information for all samples available
c. Analyze these tissues with current available technologies to better understand breast diseases.

3. Endpoint(s) to be measured

Availability of fresh, forzen tissue for current and future research, clinical studies and new technologies applied to the better understanding of breast diseases.

4. Number of subjects to be enrolled at TJU per year and in toto. These numbers should incorporate numbers screened and consented to reach enrollment.

We estimate that we should be able to store between 200 to 300 specimens a year.

5. Considerations of statistical power in relation to enrollment

N/A

6. Explain procedures that will involve the subject

There won't be particular procedures that the patients will undergo in order to participate in this project, since the tissues obtained are collected after surgery and would otherwise, be discarded.

7. Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data.

The samples will be obtained fresh from the Pathology Laboratory following their excision in the operating room. The pathologic data will be obtained from the pathology files and the clinical information will be provided by the patients themselves, who will be contacted by mail, with the referring physician's authorization and with IRB approved letter. They will be required to answer a simple questionnaire and return it to the Pathology Department.

8. Describe characteristics of the subject population, such as their anticipated number, age ranges, sex, ethnic background, and health status. The study should employ a study design with gender and race representation appropriate to the purpose of the research. Strong justification must be provided for exclusion of broad population groups. Identify the criteria for inclusion or exclusion. Explain the rationale for the use of vulnerable populations as research subjects (i.e., prisoners, pregnant women, fetuses, disabled persons, drug users, children).

All male and female patients that undergo breast biopsies and resections are eligible for the project. There are no prerequisites for the patient's samples to be stored once the appropriate diagnostic procedures have been carried out.

For all phase III clinical studies, women and members of minority groups and their subpopulations must be included, unless a clear and compelling rationale and justification is presented which shows that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Describe your plan for enrolling these populations, and any outreach programs created for this purpose.

9. Describe plans for recruitment of subjects, including advertisement and posters and the consent procedures to be followed, including the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects and the methods of documenting consent.

N/A

10. Discuss whether risks to the subject are 'minimal' or 'greater than minimal.' List the major risks of subject participation. Describe any possible benefits of subject participation. Are the risks to subjects reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result?

There is no risk for participants, since this project only deals with breast tissues received in the Laboratory. Patients will be asked to provide clinical information by answering a short questionnaire, that will be sent to them by mail.

There will be no direct benefit to a specific patient. However, future studies using the available tissues in storage will help advance and learn new insights into breast diseases for example for prevention/treatment of cancers.

11. Describe the procedures for protecting against or minimizing any potential risks, including physical, psychological, legal and confidentiality risks, and assess their likely effectiveness. Where appropriate, discuss provisions for insuring necessary medical or

professional intervention in the event of adverse events to the subjects. **Discuss your data safety monitoring plan to insure the safety of subjects.** Also, where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects. All tissues will be asssigned a random number to provide confidentiality to the patients. The Kimmel Cancer Center Shared Computer Facility develops and maintains untegrated World Wide Web database applications for shared access to cancer research related information. Moltilevel security is provided by "username/password" entry at the Web browser level, and *NT* file system and *SQL* database table permissions. The transmission of confidential information, such as patient data, is protected with 128-bit encryption.

12. If this study is a database, chart, image or other data review, are all the data already in existence? If so, what is the original time frame of their collection (from when to when)? Also, will the data be collected anonymously (meaning that only aggregate data will be collected, and there will be no names or codes maintained to match the data with the original files)?

The project was iniciated in October 2000 and will continue indefinitelly. Tissue will be stored in the breast tissue bank facility in the Department of Pathology of TJUH. The purpose of storing the tissues is to make them available for future research. Random computer generated numbers will be assigned to each sample to protect patient's identities.

13. If this proposal is a Type I NIH application/proposal, you must include children, defined as individuals under the age of 21, as subjects unless there are scientific or ethical reasons for excluding them. See below for the permissible exclusionary circumstances listed in the NIH Policy. If no exclusion applies: 1) discuss your plan for the inclusion of children; 2) justify the age range of children to be enrolled; 3) indicate the expertise of the research team with regard to children; 4) describe the facilities for the children; 5) indicate the number of children to be enrolled to give sufficient power for meaningful analysis; 6) describe how the assent process for children 7 to 18 years of age will be carried out.

The research topic is irrelevant for children.

Justify your exclusion based on one of the exclusionary circumstances listed:

- The research topic is irrelevant for children
- Children are barred by law from participation because of the risk
- Study is redundant; knowledge is being obtained in another study or is already available
- Separate age-specific children study is preferable
- Rarity of disorder makes inclusion of children extremely difficult
- The limited number of available children are already enrolled in a nation-wide pediatric disease network
- Study design precludes direct applicability to children
- Insufficient adult data to judge potential risk for children
- Study design is a follow-up of an adult study

14. This study involves research to be performed at *(check appropriate entry)*:

___TJU only
___TJU and Methodist
___Methodist only

__X_TJU and Other Institution(s) *(please specify)*_Multiple Institutions will share information and sample materials for different investigations.

REQUEST FOR WAIVER OF INFORMED CONSENT/ AUTHORIZATON TO COLLECT PROTECTED HEALTH INFORMATION*

IRB Control #___019095_____**P.I. Name**_Juan P. Palazzo, MD_____
Study Title "Breast Cancer Tissue Procurement Program and Tissue Banking Information System"

The IRB may waive the requirement to obtain informed consent/authorization provided that the investigator justifies that specific criteria included in the Privacy Rule have been met. The IRB must agree with the investigator's justification and must document the findings. To obtain a waiver of consent/authorization, all of the following conditions must be met and justified. The IRB will make the final determination as to whether the conditions have been justified based on your answers to the following questions. Use additional space if necessary.

1. Explain why the use or disclosure of Protected Health Information (PHI) involves no more than a minimal risk *to the privacy* of individuals. Include a detailed list of the PHI to be collected and a list of the source(s) of the PHI. Use additional space if needed.
    None of the researchers will have access to patient registration information, as all the cases banked are supposed to be provided with de-identified data. But in order to provide updated follow up, links to personal identifiers must be available to those members of the PI's team dedicated to data entry.
    The information will be obtained from the patients, who will be asked to answer a simple questionnaire, mailed with their referring physician's authorization.
    The PHI we intend to collect includes:
    -First and Last name
    -Social Security Number
    -Medical Record Number
    -Insurance Carrier
    -Insurance Number
    -Address (street, city, state and zip code)
    -Telephone Number

2. This research presents no more than minimal risk *to the subjects* because:
    Only de-identified information will be disclosed. No clinical information will be linked to personal data.

3. The waiver or alteration will not adversely affect the rights and welfare of the subjects because:
    Only de-identified information will be provided to researchers. Results will not be referred back to patients or their physicians and will not be added to their clinical record.

4. Investigators are required to only obtain the minimum necessary PHI in order to achieve the goals of the research. Please justify why the data you wish to obtain is the minimum necessary to achieve the goals of the research.
    Along with banked samples we intend to be able to provide information on follow up and response to therapy. PHI are necessary in order to obtain long term follow up and outcome that can be correlated with investigation results.

5. The research could not be practicably carried out without the waiver or alteration because (please note inconvenience, time and resources are not acceptable criteria):
    Patient demographic information is not available to the pathology department.

6. The research could not practicably be conducted without access to and use of PHI because:
    In order to understand pathogenesis, progression and outcomes of breast tumors, not only breast tissues but also clinical information is required.

    *Protected Health Information: Individually identifiable health information transmitted or maintained in any form (electronic means, on paper, or through oral communication) that relates to the past or future physical or mental health or conditions of an individual.

7. Please describe the steps taken to assure privacy and confidentiality of subject data and to protect the identifiers/links to identifiers from improper use or disclosure. If links to identifiers are used, please describe the coding mechanism.
    Breast tissues to be banked are selected depending on the amount of tissue available. Specimen numbers are computer generated at the time of tissue banking and are used, from that moment on, to identify the samples and the clinical information. The database is firewall and password protected, so PHI is available only to the person dedicated to data entry in the PI's team. No researcher has access to patient's registration information and the clinical information can be linked only to the bank number. Access to the firewall protected database will be granted hierarchically by an IRB approved administrator and a password will be required, so they will be able to access clinical information but not to PHI.

8. Identifiers (or links) should be destroyed at the earliest possible time. Please describe your plans and specify when this will occur. However, if there is a justification for retaining the identifiers, please provide this information. (For protocols that may be subject to future continuing and secondary data analysis, provide a justification for not destroying identifiers indefinitely).
    As this is a longitudinal study, we need to keep links to identifiers, in order to update information, but these links will be restricted only to the person responsible for data entry.

9. If appropriate, how will subjects be provided with additional pertinent information after participation? If not appropriate, please specify why.

Patients will be contacted by mail, after banking their tissues and with authorization from the referring physician, and will be asked to answer a simple and short questionnaire, in order to obtain clinical information.

No investigation results will be referred back to the patients or their physicians and will not be placed in their medical records, as all the information provided to researchers will be de-identified.

The information listed in the waiver application is accurate and all study personnel will comply with the HIPAA regulations and the waiver criteria. All study personnel have completed HIPAA training.

Principal Investigator Signature_____Date_____

For DHSP Use Only

☐ The IRB has determined that in accordance with the regulations of the HIPAA Privacy Rule 45 CFR Parts 160 and 164, criteria for waiver of authorization/and consent cannot be met and authorization/consent is required.

_____De-identified (use or disclose--no further requirements)
_____Limited Data Set (use or disclose--Data Use Agreement required)
_____Identified
    _____Authorization Obtained
     or
    _____Waiver of Authorization granted
    _____Use
    _____Disclosure (outside TJU)
    _____Greater than 50 (modified tracking) or
    _____Less than 50 (full tracking)

THOMAS JEFFERSON UNIVERSITY INSTITUTIONAL REVIEW BOARD
Continuing or Final Review of Research Protocols Involving Human Subjects
(Complete all items - Form must be typewritten)

TYPE OF REVIEW: [X] CONTINUING REVIEW/ANNUAL   [   ] FINAL REVIEW

IRB CONTROL NO: **01.9095**_____   DATE OF <u>FIRST</u> IRB APPROVAL:
2/08/01 _____

DATE OF <u>LAST</u> ANNUAL IRB APPROVAL:

2/12/03_
INITIAL REVIEW WAS <u>FULL</u> ( ) or <u>EXPEDITED</u> (X)   DATE OF FIRST SUBJECT ENROLLMENT:
         6/08/00_
                        (Noted on approval letter)

TITLE OF PROTOCOL: "Breast Cancer Tissue Procurement Program and Tissue Banking Information
System"_____

PI AND CO-Is: PI: Juan P. Palazzo, MD
                        CO-Is: Jack London, Ph.D. and Alejandra Ruiz Orrico, MD_____

DEPARTMENT: Pathology, Anatomy and Cell Biology_____FUNDING AGENCY: N/A_____

Subject Summary: Please provide the following subject information:

1. Projected enrollment at TJU approved by IRB: per year:_____   total for study:_____
   (*This form will consider "enrolled" to mean those subjects successfully retained/*   **Since Last**
Total to
   randomized on a study.)   **Approval**   **Date**

2.Total number of subjects screened for enrollment at TJU *(and satellite sites, if*   N/A   N/A
applicable):

3. Total number of subjects enrolled *(after screening)*:   156   561

4. Date when last on-site subject was enrolled: _12/29/03_____

5. Number of serious adverse events occurring at TJU in the past year currently noted in
   consent form *(please list adverse events)*:   N/A   N/A

6. Number of serious adverse events occurring at TJU in the past year <u>not</u> currently noted
   in consent form *(please list adverse events)*:   N/A   N/A

**Please attach adverse event summary included with your continuing review reminder letter, if
applicable.**

_X_This report of continuing review ***does not include*** any increased risks to subjects enrolled since last
   report. (Current subject risk profile remains unchanged.)

___This report of continuing review ***does include*** increased risks to subjects currently enrolled in the
protocol.
   Consent form risk profile has been revised. Please explain revisions below:

Demographic Data: Provide the number of on-site subjects enrolled in the study to date, according to
classification. See Table.
                        (Total should be equal to #3 in Subject Summary).

	Native American	Asian	Black Non-Hispanic	Hispanic	White Non-Hispanic	Other/ Unknown	**TOTAL TO DATE**
Adult-Female							
Adult-Male							
Child-Female							
Child-Male							
TOTAL TO DATE							561

DIRECTIONS: For a study initially given a full review, submit 35 collated sets of the following items: OSA-9, updated OSA-2, adverse event summary (included with continuing review reminder letter), current stamped consent form, clean updated consent form. Also provide <u>one</u> <u>complete copy</u> of the current protocol. For a study initially given an expedited review, submit 4 collated sets of same materials. All final reviews should be submitted in 4 copies. *If study was approved for collection of biological specimens, include copy of approval letter.*

Progress Report: IRBs are federally mandated to review a progress report for all reports of continuing review. Please summarize the past year's on-site research and subject progress. *Include*: 1) subject response to treatment/procedures, 2) withdrawals from study, 3) data analysis, 4) presentations/publications of research, 5) subject grievances or complaints, and 6) summary of amendments submitted within the past year and changes in key personnel. (Use separate sheet for progress report, and for other questions as needed.)

Audit/Site Visit: Have you had an audit or site visit within the past year? Yes___ No X   If yes, please attach report(s).

Multi-center Trials:

Have there been any relevant reports issued by the sponsor or cooperative group for this study? Yes___ No X If yes, please attach report(s).

Has a Data & Safety Monitoring Board (DSMB), Data Monitoring Committee (DMC) or sponsor reviewed study-wide adverse events and interim findings? Yes___ No_X If yes, please attach report(s).

Literature Review: As Principal Investigator of this study, I certify that I have conducted a review of the relevant literature published in the past year, and I have found that the literature indicates:

[X] No change in the risk/benefit ratio for subjects on this study, and no cause for subjects to reconsider their participation in the
    study.
[ ] Change in the risk/benefit ratio for subjects on this study and/or cause for subjects to reconsider their participation in the
    study. *Please explain and cite relevant articles.*

Enrollment: Has the enrollment for the past year been greater or less than projected? Explain. If the enrollment has been less than projected, has this impacted on the statistical validity of the study?

Recruitment/Payment: Have there been any modifications to recruitment procedures and/or subject payment? If yes, was an RO-12 submitted?

Current Study Status:

_X_ Study is active and subject recruitment is ongoing.

___ Enrollment is closed. However, subjects are currently receiving study treatment. (*A new stamped consent form will not be issued*.)

___ Enrollment is closed. Subjects are not receiving study treatment. Follow-up involves following for survivorship and/or treatment or testing that would not be done off-protocol. (*A new stamped consent form will not be issued*.)

___ Study is closed. This represents the final report.

Certification: We certify that the information contained above is correct, that the consent form currently reflects any and all modifications since the last approval by the Institutional Review Board, and that: [check where relevant]

[X]   **Under federal mandate, there is a signed consent form on file with the principal investigator for every subject studied at TJU, and each subject at TJU has received a signed copy of the consent form.** *(If this is not true, please provide a brief explanation. Do not check if no subjects enrolled)*

OR

[ ]   **The Institutional Review Board approved the study without a need to obtain written consent from subjects.**

****

_____ 215-503-

5050_____

Signature of Individual Completing This Report   Date   Telephone and/or Pager
Number

_____ 215-955-4403_____

_____

Principal Investigator   Date   Telephone and/or Pager Number

**If you have not updated your consent form (OSA-8) within the past year, please take the time to do so, per the current IRB consent form template, available from the IRB office or IRB website. Please review your consent form for grammatical correctness, spelling & legibility. Thank you.

Progress Report

The recruitment of surgical specimens continue to grow. The tumor bank has 561 breast cancer samples
that are being utilized by Jefferson and non Jefferson researchers. The corresponding IRB documents from these
collaborators have been filed with the Jefferson IRB. Clinical information is being obtained at a slower pace but also in compliance with the approved IRB documents for each patient.

_____ 215-503-

5050_____

Signature of Individual Completing This Report   Date   Telephone and/or Pager
Number

_____ 215-955-4403_____

Principal Investigator   Date   Telephone and/or Pager Number

APPENDIX D: Materials Transfer Agreement

NOT APPLICABLE

APPENDIX E: SAMPLE REPORT

SurgPathNum	StudyNumber	AccDate	TumorBank	SpecType	SiteLesion	LNexcision	TypeLNexcision
S00-19215	1	10/3/2000	no	Modified radical mastectomy	Left - Upper Inner Quadrant	yes	Axillary lymph node dissection w/o designated leve
S00-19178	100	10/2/2000	yes	Lumpectomy w/o margins		no	
S00-19248	101	10/3/2000	yes	Modified radical mastectomy		yes	Axillary lymph node dissection w/o designated leve
S00-11077	102	6/8/2000	yes	Modified radical mastectomy		yes	Axillary lymph node dissection w/ designated level
S00-13667	103	7/17/2000	yes	Lumpectomy w/o margins		no	
S00-18854	104	9/27/2000	yes	Lumpectomy w/o margins	Left - Upper Outer Quadrant	yes	Axillary lymph node dissection w/o designated leve
S00-12652	105	6/30/2000	yes	Lumpectomy w/ separate margins		no	
S00-12591	106	6/29/2000	yes	Lumpectomy w/o margins		no	
S00-23765	107	12/5/2000	yes	Modified radical mastectomy	Left - Upper Outer Quadrant	yes	Axillary lymph node dissection w/o designated leve
S00-24190	108	12/11/2000	yes	Lumpectomy w/ separate margins	Right - Quadrant NOT SPECIFIED	no	
S00-24388	109	12/13/2000	yes	Modified radical mastectomy	Left - Lower Inner Quadrant	yes	Axillary lymph node dissection w/ designated level
S00-24315	113	12/12/2000	yes	Modified radical mastectomy	Right - Upper Inner Quadrant	yes	Axillary lymph node dissection w/ designated level
S00-24269	114	12/11/2000	yes	Lumpectomy w/o margins		no	
S00-24611	115	12/15/2000	yes	Lumpectomy w/ margins		no	
S00-25436	115	12/29/2001		Modified radical mastectomy		yes	Axillary lymph node dissection w/o designated leve
	115						
S00-25113	116	12/22/2000	yes	Lumpectomy w/ separate margins		no	
S00-25121	117	12/22/2000	yes	Lumpectomy w/ separate margins	Right - Upper Outer Quadrant	no	
S00-25167	118	12/26/2000	yes	Modified radical mastectomy	Right - Upper Outer Quadrant	yes	Axillary lymph node dissection w/o designated leve
S00-24221	119	12/11/2000	yes	Lumpectomy w/ margins	Left - Upper Outer Quadrant	no	
S00-23483	120	11/30/2000	yes	Radical mastectomy		yes	Axillary lymph node dissection w/o designated leve
S00-23723	121	12/4/2000	yes	Lumpectomy w/o margins		no	

ID	Num	Date		Procedure	Location		Additional
S00-23587	122	12/1/2000	yes	Lumpectomy w/ separate margins		no	
S00-23184	123	11/28/2000	yes	Modified radical mastectomy	Right - Lower Outer Quadrant	yes	Axillary lymph node dissection w/ designated level
S00-24970	124	12/20/2000	yes	Lumpectomy w/o margins		no	
S01-00344	125	1/5/2001	yes	Modified radical mastectomy	Right - Lower Outer Quadrant	yes	Axillary lymph node dissection w/ designated level
S00-24736	125	12/18/2000	yes	Other		no	
S00-25218	126	12/27/2000	yes	Modified radical mastectomy		yes	Axillary lymph node dissection w/o designated leve
S00-25254	127	12/27/2000	yes	Reduction mammoplasty		no	
S00-22150	128	11/10/2000		Lumpectomy w/ margins		no	
S00-22086	129	11/10/2000	yes	Lumpectomy w/o margins		no	
S00-24319	130	12/12/2000	yes	Lumpectomy w/o margins		no	
S00-25038	131	12/21/2000	yes	Other		no	
S00-24608	132	12/15/2000	yes	Lumpectomy w/ separate margins		no	
S00-25004	133	12/21/2000		Modified radical mastectomy		yes	Axillary lymph node dissection w/ designated level
S00-23319	134	11/29/2000	yes	Lumpectomy w/o margins		no	
S00-23561	135	12/1/2000		Reduction mammoplasty		no	
S00-23444	136	11/30/2000	yes	Reduction mammoplasty		no	
S00-24091	137	12/8/2000	yes	Lumpectomy w/ separate margins		no	
S01-00374	138	1/5/2001	yes	Lumpectomy w/ separate margins	Left - Upper Inner Quadrant	no	
S01-00204	140	1/4/2001		Lumpectomy w/o margins		no	
S01-00141	141	1/3/2001		Reduction mammoplasty		no	
S01-00045	142	1/2/2001	yes	Reduction mammoplasty		no	
S01-00044	143	1/2/2001		Modified radical mastectomy	Left - Lower Outer Quadrant	yes	Axillary lymph node dissection w/ designated level
S01-00003	144	1/2/2001	yes	Lumpectomy w/ separate margins		no	
S01-8131	145 145	4/23/2001	yes	Modified radical mastectomy		yes	
S01-1488	148	1/19/2001	yes	Lumpectomy w/o margins			
S01-1505	149	1/19/2001	yes	Lumpectomy w/ separate margins	Left - Upper Outer Quadrant	no	
S01-1684	150	1/22/2001	yes	Lumpectomy w/o margins		no	
S01-2717	151	2/5/2001	yes	Lumpectomy w/o margins		no	
S01-2263	152	1/30/2001	yes	Radical mastectomy	Left - Upper Outer Quadrant	yes	Axillary lymph node dissection w/o designated leve
S01-2861	153	2/6/2001	yes	Reduction mammoplasty		no	
S01-3274	154	2/12/2001	yes	Lumpectomy w/o margins		no	

S01-2729	155	2/5/2001	yes	Lumpectomy w/ separate margins		no	
S01-3354	155	2/13/2001	yes	Other		yes	Sentinel node biopsy
S01-2762	156	2/5/2001	yes	Lumpectomy w/ separate margins		no	
S01-2764	157	2/5/2001	yes	Lumpectomy w/ separate margins		no	
S01-3442	158	2/13/2001	yes	Simple mastectomy	Left - Upper Inner Quadrant	no	
S01-3327	159	2/12/2001	yes	Lumpectomy w/ separate margins		no	
S01-3114	160	2/9/2001	yes	Lumpectomy w/ separate margins		no	
S01-3137	161	2/9/2001	yes	Modified radical mastectomy	Left - Upper Inner Quadrant	yes	Axillary lymph node dissection w/ designated level
S01-3115	162	2/9/2001	yes	Lumpectomy w/ separate margins		no	
S01-3013	163	2/8/2001	yes	Lumpectomy w/o margins			
S01-9326	164	5/1/2001	yes	Modified radical mastectomy		yes	Axillary lymph node dissection w/o designated leve
S02-4320	164	2/26/2002	yes	Modified radical mastectomy	Right - Lower Outer Quadrant	yes	Axillary lymph node dissection w/ designated level
S01-3446	165	2/14/2001	yes	Lumpectomy w/o margins		yes	Axillary lymph node dissection w/o designated leve
S01-3592	166	2/15/2001	yes	Modified radical mastectomy		yes	Axillary lymph node dissection w/o designated leve
S01-3571	167	2/15/2001	yes	Simple mastectomy	Left - Lower Inner Quadrant	yes	Axillary lymph node dissection w/o designated leve
S01-3702	168	2/16/2001	yes	Lumpectomy w/o margins		no	
S01-3826	169	2/19/2001	yes	Reduction mammoplasty			
S01-3831	170	2/19/2001	yes	Lumpectomy w/ separate margins		no	
S01-4376	170	2/27/2001	yes	Lumpectomy w/ separate margins		yes	Axillary lymph node dissection w/ designated level
S01-4369	171	2/26/2001	yes	Lumpectomy w/ separate margins		no	
S01-4204	172	2/23/2001	yes	Reduction mammoplasty		no	
S01-4197	173	2/23/2001	yes	Lumpectomy w/ separate margins		no	
S01-4565	174	2/28/2001	yes	Lumpectomy w/o margins		no	
S01-4564	175	2/28/2001	yes	Lumpectomy w/o margins		no	
S01-4530	176	2/28/2001	yes	Reduction mammoplasty		no	
S01-4655	177	3/1/2001	yes	Reduction mammoplasty			
S01-4602	178	3/1/2001	yes	Lumpectomy w/o margins		no	

S01-4632	179	3/1/2001	yes	Lumpectomy w/ separate margins		yes	Axillary lymph node dissection w/o designated leve
S01-5203	180	3/9/2001	yes	Modified radical mastectomy		yes	Axillary lymph node dissection w/ designated level
S01-4702	181	3/2/2001	yes	Lumpectomy w/ separate margins		no	
S01-4654	182	3/1/2001	yes	Lumpectomy w/o margins		no	
S01-4581	183	2/28/2001	yes	Lumpectomy w/ margins		no	
S01-5640	184	3/15/2001	yes	Lumpectomy w/ separate margins	Left - Quadrant NOT SPECIFIED	no	
S01-5773	185	3/16/2001	yes	Lumpectomy w/ margins	Left - Quadrant NOT SPECIFIED	no	
S01-5640	186	3/15/2001	yes	Lumpectomy w/ separate margins	Left - Quadrant NOT SPECIFIED	no	